REMARKS/ARGUMENTS

This paper is responsive to the Office Action mailed on July 3, 2007, in the above-captioned application. In response to the Office Action, which has been carefully reviewed, claim 1 has been amended, and claims 32-33 have been canceled without prejudice or disclaimer. No new matter has been added.

Additionally, the specification has been amended to insert the application number of a U.S. patent application that was unknown at the time of filing of the present application. No new matter has been added.

Claim Objections

Claim 1 stands objected to because the claim listing in the amendment of 19 April 2007 does not accurately match the previous claim listing. The failure to underline "based upon the" on line 6 of claim 1 and the omission of the "compiling a data set" language in the Amendment dated April 19, 2007, were inadvertent errors. Claim 1 has been amended to clarify the intended claim language. Accordingly, withdrawal of this objection is respectfully requested.

Rejection under 35 U.S.C. § 112

Claim 2 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation "in response to electronic selection of the intervention flag" was first presented in claim 2 in the Amendment and Response dated February 22, 2005. This language was not added in the Amendment of April 19, 2007. Also, this functionality is also described, for example, at page 17, line 9 to page 18, line 4, of the Specification. Accordingly, no new matter has been added, and withdrawal of this rejection is respectfully requested.

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. However, claim 1 has been amended to correct this informality, and therefore withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 1-11 and 32-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lash (2001/0020229) in view of Trusheim et al. (U.S. 6,385,589).

I. The Applied Art

Lash describes a system and method for predicting the likelihood that a patient having one disease or condition will acquire high medical service utilization characteristics. A probability equation is applied to patient claim data to calculate a probability value indicative of the likelihood that a patient will have a high utilization of healthcare resources within a given period of time. See Lash Abstract.

The Lash reference describes two methods, a method for developing a probability equation using healthcare claim data for a homogeneous grouping of patients, i.e., patients all having a certain diagnosis or disease, and a method for using the probability equation to calculate a probability value for each patient in a similarly homogeneous group of patients. Lash at ¶ 0046. The probability equations produced by the Lash method are "based on a particular disease diagnosis." Lash at ¶ 0047.

To develop its probability equation of each particular disease diagnosis, the Lash method identifies high relevance claim variables from a preselected subset of the total possible claim variables for a homogeneous grouping of patients. The high relevance variables are selected by the process of logistical regression analysis modeling. In addition, weighting coefficiently are also determined using logical regression modeling. An assortment of possible claim variables is described in Lash at ¶ 0049, and the high relevance variables identified for asthmatic patients are described in ¶¶ 0050-52. The Lash method produces a risk score for each patient in the homogeneous group.

However, Lash does not describe or suggest calculation of a risk score that enables comparison of multiple patients will multiple diseases or conditions. Lash states that

> "[i]t is very difficult to create accurate models with diverse populations of patients because they have very different motivations that control their behavior. However, it has been discovered that patients suffering from a particular disease or condition behave in very similar fashions as regards their medical treatment. Therefore, if the population is not otherwise homogeneous, it is filtered, for example on the basis of the disease or diagnosed condition of the patient to filter the population into more homogeneous sub-populations in step 65. As an example the population of patients can be segregated in the filter step 65 into asthma patients, diabetic patients, etc."

Lash at ¶37 (emphasis added). Thus, Lash does not teach or suggest the calculation of predicted future healthcare utilization for each of the plurality of members that is calculated to enable comparison of the predicted future healthcare utilizations of members having different diseases or health conditions, as recited in amended claims 1, 32 and 33. To the contrary, **Lash expressly confirms the difficulty of calculating a predictive value for non-homogeneous populations (having multiple diseases or conditions) and does not suggest any method for accomplishing such a calculation.**

Trusheim describes a system for managing the health care of a plurality of members in a population that includes storage of member characteristics and medical data (including claims and test results). Stored and newly received member information is assessed by a program to determine whether the member information meets certain predefined rules or criteria. If so, a notification or alert message is automatically generated and transmitted to a care provider, administrator, etc. to enable the recipient to take appropriate steps to assist the patient.

The Trusheim methodology for identifying patients for intervention is different from Lash in that, *inter alia,* it (1) is rule-based and (2) is not expressly limited to a particular disease or condition. The Trusheim method is rule-based in that it uses data repository program 44 to check incoming and stored patient data to see whether the data matches defined rule criteria. As described in Trusheim,

> "[d]ata repository program 44 preferably generates special notifications, called clinical alerts, by examining member characteristics, historical member-related data, and medical events data. Generally, clinical alerts are notifications based on an analysis of data from various data sources stored within the system. For example, a patient who is over 75 years old, has a history of episodic atrial fibrillation, is allergic to aspirin, and is not receiving Ticlopidine or Clopidigril is

> at risk for acute myocardial infarction. Therefore, a clinical alert may be designed to detect whether any patients possess these characteristics and, if so, to issue a clinical alert notification and intervention information for addressing the risk situation."

Trusheim at col. 10, lines 50-62. Thus, Trusheim identifies patients for intervention based upon a programmed set of rules that identify different combinations of specific medical conditions, member characteristics and/or medical events that trigger an intervention notification.

Additionally, the Trusheim system is not limited to assessment of patients having a particular disease or condition, but instead a member population having numerous diseases and conditions:

> "For example, the following combinations of member characteristics and/or medical events represent risk situations: diabetes, hypertension and high sodium levels, dementia and no caregiver support, heart problems and no prescribed beta blockers, discharge of an elderly patient who lacks caregiver support, and presence of a chronic condition, a hospitalization medical event, and no caregiver support."

Trusheim at col. 4, lines 19-26. Thus, the Trusheim system is designed to manage a member population with multiple diseases and conditions by utilizing a program (44) that is programmed to apply specific rules for different combinations of diseases, conditions, member characteristics and medical events, wherein the programmed rules are the basis for the intervention notifications generated by the system.

II. The Asserted Combination Does Not Disclose or Suggest All of the Features Recited in Amended Claims 1, 32, and 33 as Required For a *Prima Facie* Case of Obviousness Under § 103

The PTO has the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. "The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." MPEP § 2142. "To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach

or suggest all of the claim limitations." MPEP 2143. *See also* MPEP 2143.03 (citing In re Royka, 490 F.2d 981 (CCPA 1974)).

The asserted combination of Lash and Trusheim does not disclose or suggest all of the limitations of the present invention as recited in amended claim 1. First, neither Lash nor Trusheim discloses or suggest the storage of healthcare data and **a predicted future healthcare utilization for each of a plurality of members of a healthcare plan, wherein the members having a plurality of diseases or health conditions**, and **wherein the predicted future healthcare utilization for each of the plurality of members is calculated to enable comparison of the predicted future healthcare utilizations of members having different diseases or health conditions**.

Specifically, Lash does not disclose a predicted future healthcare utilization that is calculated to enable comparison of the predicted future healthcare utilizations of members having different diseases or health conditions. As quoted above, Lash teaches away from such a utilization due to the unpredictability of non-homogeneous patients, stating that such a calculation would be difficult and therefore not attempting any such calculation. Instead, Lash calculates a predicted future cost value for a more predictable, homogeneous sub-population of members all having the same disease or condition. Also, Trusheim does not teach or suggest the recited predicted future healthcare utilization for each member of a health plan. Thus, the asserted combination does not describe or suggest the claimed functionality.

Second, the asserted combination of Lash and Trusheim does not disclose or suggest selecting one or more high-risk members from the plurality of members (having a plurality of diseases or health conditions) based upon the members' respective predicted future healthcare utilizations, wherein the selected high-risk members have a plurality of diseases or health conditions. While Lash teaches the use of a predicted future cost to select high-cost patients from the homogeneous sub-group of patients with the same disease (see Lash at ¶ 41), Lash teaches away from the calculation of the predicted future healthcare utilization as defined in amended claim 1 that would enable selection of high-risk patients having a plurality of diseases or health conditions due to the difficulty of such a calculation. Additionally, Trusheim does not

disclose or suggest the use of a predicted future healthcare utilization to select high-risk members. As discussed above, Trusheim utilizes a rule-based program to identify intervention patients. Thus, the asserted combination does not describe or suggest the claimed functionality.

Third, neither Lash nor Trusheim nor the combination thereof describes or suggests compiling a data set including all stored healthcare data associated with each selected high-risk member as recited amended claim 1. Lash does not teach the creation of the recited non-homogeneous group of high-risk members, and therefore does not teach or suggest the compilation of data associated with such a member group. Trusheim discloses collection of data for all members of the population as well as creating access to data associated with patients selected for intervention based upon the programmed rules, which are not the high-risk members as defined in claim 1. Thus, the asserted combination does not describe or suggest the claimed functionality.

Fourth, neither Lash nor Trusheim nor the combination thereof describes or suggests searching the stored healthcare data associated with each selected high-risk member to identify the presence of at least one intervention flag for the member, wherein each intervention flag corresponds to a member attribute amenable to intervention as recited in amended claim 1. As conceded by the Examiner, Lash does not teach or suggest the use intervention flags to identify patients for intervention. Trusheim teaches the use of programmed rules to identify patients for intervention. Assuming *arguendo* that the rules taught by Trusheim are comparable to the intervention flags of the present invention, Trusheim uses its rules to analyze all the data from all members of the population, and not to a high-risk subset of the population as described in amended claim 1. Nor does Trusheim suggest creating any subset of the population to evaluate using its intervention rules.

Moreover, the combination of Lash and Trusheim together would not achieve the claimed functionality because neither reference teaches or suggests creation of a high-risk subgroup of members having a plurality of diseases or health conditions and searching the high-risk member data for intervention flags. Just as neither reference describes or suggests the claimed functionality, the references in combination also do not teach the claimed functionality.

Fifth, neither Lash nor Trusheim discloses or suggests selecting an intervention group of the high-risk members, each member of the intervention group having a selected number or type of intervention flags as recited in amended claim 1. As conceded by the Examiner, Lash does not teach or suggest the use intervention flags to identify patients for intervention, and thus does not teach or suggest the claimed selection of an intervention group. As discussed above, Trusheim teaches the use of programmed rules to identify patients for intervention. Assuming *arguendo* that the rules taught by Trusheim are comparable to the intervention flags of the present invention, Trusheim applies its rules to analyze medical data from all members of the population, and not to a high-risk member subset of the population as described in amended claim 1. Nor does Trusheim suggest creating any subset of the population of members to evaluate for intervention, which would enable selection of a second subset of the population representing the claimed intervention group.

Moreover, the combination of Lash and Trusheim together would not achieve the claimed functionality because neither reference teaches or suggests creation of an intervention group as a subset of a high-risk group of members having a plurality of diseases or health conditions. Just as neither reference describes or suggests the claimed functionality, the references in combination also do not teach the claimed functionality.

In contrast to both Lash and Trusheim, the present invention provides a method of using a predicted future healthcare utilization that enables comparison of members having different diseases of health conditions (i.e., non-homogeneous population) to identify high-risk patients having a plurality of disease or health conditions. Neither Lash nor Trusheim nor the combination thereof is teaches or suggests a means of accomplishing this functionality. Lash recognizes the difficulty of calculating such a utilization for non-homogeneous members and therefore does not attempt to calculate comparative future cost values for members with different diseases or conditions. Trusheim also does not disclose or suggest a predicted future healthcare utilization that is utilized to identify high-risk members from the general population of members. Instead, the Trusheim system evaluates data from all of the population members to identify intervention patients. This is in contrast to the present invention in which only the high-risk member data is searched for intervention flags.

The Examiner states that "it is the entire combined applied reference(s) that must be considered when evaluating whether or not the applied references teach the cited limitations" and that "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references" (citing In re Keller, 642 F.2d 413 (CCPA 1981) and In re Merck & Co., 800 F.2d 1091 (Fed. Cir. 1986). Office Action at pp. 18-19. However, when neither reference discloses or suggests one or more claimed limitations, and, as here, one of the references expressly teaches away from a central limitation due to difficulty in accomplishing it, it is proper to conclude that the claimed invention is not obvious over asserted combination.

Moreover, "the test [for obviousness] is what the combined teachings of the references would have suggested to one of skill in the art." In re Keller, 642 F.2d at 425. In this instance, the two asserted references teach fundamentally different methods of identifying patients for intervention. The asserted references would not have suggested, either alone or in combination, the claimed method in which a predicted future healthcare utilization that enables comparison of members with different diseases or health conditions is used to select high-risk members with different diseases or health conditions, healthcare data is compiled for the high-risk members, the high-risk member healthcare data is searched for intervention flags, and an intervention group of members is selected from the high-risk member group based upon the identification of intervention flag in the high-risk member's healthcare data.

For these reasons, the asserted combination of Lash and Trusheim does not teach all of the features recited in amended claim 1. Therefore, the Examiner has not established a *prima facie* case of obviousness required under 35 U.S.C. § 103 and as described, for example, in M.P.E.P. § 2143 (requiring, *inter alia*, that the combination of references teach all limitations recited in the claim). Accordingly, amended claim 1 is not obvious under §103 and should be allowed.

III. One of Ordinary Skill in the Art Would Not Have Been Motivated to Make the Asserted Combination

Additionally, one of ordinary skill in the art would not have been motivated to combine Lash and Trusheim to achieve the claimed invention as asserted by the Examiner for the following reasons.

Lash and Trusheim teach two fundamentally different approaches as to how to identify patients for whom intervention is desirable. Lash teaches the calculation of a predicted cost value for a group of patients all having the same disease or condition and uses the calculated values to identify the highest-cost patients in the homogeneous group, while Trusheim uses a rule-based approach to identifying members of a non-homogeneous population for intervention. Absent the roadmap provided by the present invention, there would have been no motivation for one of ordinary skill in the art to additionally analyze the data of the high-cost members of the homogeneous group identified for intervention in Lash using the intervention rules taught by Trusheim as asserted by the Examiner. Each of the references teaches a different methodology for identifying intervention patients. One (Lash) calculates a predicted future cost for a filtered set of homogeneous patients and uses the predicted future cost value to identify patients for intervention. The other (Trusheim) analyzes medical information collected for all members of a non-homogeneous population using a set of defined rules to identify intervention patients. It is not logical to conclude that it would have been obvious for one of skill in the art, reading both references, to combine these two fundamentally different systems to achieve the claimed invention. This is particularly true where, as here, one of the references teaches away from a central limitation of the claimed invention due to its difficulty and unpredictability.

It is also unreasonable to conclude that further analysis of the high-cost members identified in Lash using an intervention rule program as taught by Trusheim as asserted by the Examiner would in any way provide "a flexible and proactive system to improve the health of a population of member patients" or "lower the costs of caring for the population by detecting risk situations and allowing care providers to proactively address avoidable process failures that correspond to the risk situations.'" Office Action at p. 9. There simply is no evidence to

suggest that the use of intervention rules to analyze the healthcare data of the high-cost members all having the same disease of condition would achieve any such benefits.

For the reasons set forth above, amended claim 1 is believed to be patentable over Lash and Trusheim.

IV. Dependent Claims

Claims 2-15 depend from amended claim 1 and are believed to be patentable over the applied references for at least those reasons set forth above with respect to amended claim 1.

In addition to the features of amended claim 1, amended claim 7 also recites calculation of a future cost for each member of the intervention group, a feature that is not taught or suggested by Lash or Trusheim.

Also, with reference to amended claims 8 and 9, neither Lash nor Trusheim teaches the calculation of a relative risk or relative risk ranking for each member based upon the predicted healthcare utilization for each member as recited in amended claims 8-9.

Dependent claims 12-13, which depend from amended claim 1, stand rejected under 35 U.S.C § 103(a) as being unpatentable over Lash (2001/0020229) and Trushiem et al., U.S. Patent No. 6,385,589, as applied to claim 1 and further in view of U.S. Application Publication No. 2003/0167189A1 to Lutgen. While Lutgen describes the use of groupings of claim data by medical episode, it does not teach or suggest the features described in amended claim 1. Therefore, given the deficiencies of the Lash and Trusheim references discussed in detail above, claims 12-13 are believed to be patentable over the asserted combination of references for at least those reasons set forth above with reference to amended claim 1.

Claims 14-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lash (2001/0020229), Trushiem et al. U.S. Patent No. 6,385,589 and U.S. Application Publication No. 2003/0167189A1 to Lutgen. However, Lutgen does not teach or suggest the features recited in claim 1 that are missing from Lash and Trusheim, as discussed above. Therefore, claims 14-15 are believed to be patentable over the asserted combination of references for at least those reasons set forth above with reference to amended claim.

CONCLUSION

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

The fee required to obtain a two-month extension of time is filed herewith, making this a timely filed response. The Commissioner also is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment, to Deposit Account No. 04-1420.

Respectfully submitted,

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